REMARKS

Claims 1, 2, and 4-7, 9-12, and 14 will be pending upon entry of this Amendment D. Claim 1 has been amended to require the gas-impermeable cover to include a plurality of portions detachably mounted to the outer surface of the gas-permeable first layer. Support for this amendment can be found in originally filed claim 8, in the instant Specification at page 8, lines 18-25, and Figure 4. Claim 1 has also been amended to require that at least one of the plurality of portions includes information related to heat generated by the heat patch when one or more or the plurality of portions is removed from the gas-permeable layer. Support for this amendment can be found in originally filed claim 13 and in the instant Specification at page 10, lines 7-9. Claims 9, 12, and 14 have been amended to depend from claim 1. Claims 8 and 13 have been cancelled.

Applicants respectfully request reconsideration and allowance of all pending claims.

1. Rejection of the Claims 1-2 and 4-8 under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 1, 2, and 4-8 under 35 U.S.C. §103(a) as being unpatentable over Zhang, et al. (U.S. Patent No. 5,658,583) in view of Usui (U.S. Patent No. 5,879,378).

Claim 1, as amended herein, is directed to a heat patch comprising an enclosure that includes a gas-permeable first layer and a second layer such that a perimeter of the gas-permeable first layer is bonded to a perimeter of the second layer. The gas-permeable first layer includes an inner surface

and an outer surface, wherein said entire first layer is gas-permeable. The heat patch also includes a heating composition inside the enclosure, wherein the heating composition is capable of generating heat when a gas is received through the gas-permeable first layer. In addition, the heat patch includes a gas-impermeable cover that is detachably mounted to the outer surface of the gas-permeable first layer. The gas-impermeable cover includes a plurality of portions detachably mounted to the outer surface of the gas-permeable first layer, wherein at least one of said plurality of portions includes information related to heat generated by the heat patch when one or more of said plurality of portions is removed from said gas-permeable first layer.

Zhang, et al. disclose an apparatus, product formulation, and method for improved dermal penetration of pharmaceuticals. The apparatus includes a drug formulation reservoir and a heat-generating chamber separated by a first non-permeable wall. The reservoir and chamber are formed in or supported by a housing which may be formed completely or partially of a thermal insulating material. The heat generating chamber (heating element) includes means for generating controlled heat, and preferably, the heat generating means is a chemical composition made of carbon, iron powder, water, and/or salt which is activated upon contact with air. The heat generation chamber is capped by a structure which has substantially non-air permeable areas such as areas preferably formed with good thermal insulating material, such as closed-cell foam tapes, and openings or areas comprising material with desired permeability to air. Alternatively, the entire structure may be made of

semipermeable membrane with desired air permeability. The entire device is stored in an air-tight packaging, or container, or a removable barrier is employed to cover the semipermeable membrane(s) or openings to prevent premature activation of the heat-generating medium. One means to reduce the air flow rate to the heat-generating medium is to place a few small pieces of tape in a convenient place on the device. The tape can be peeled off and placed on top of the opening(s), the semipermeable membrane area(s) or the semipermeable membrane surface to reduce air flow and thus temperature.

Significantly, as recognized by the Office, Zhang, et al. fail to disclose a heat patch comprising an enclosure that includes a gas-permeable first layer and a second layer such that a perimeter of the gas-permeable first layer is bonded to a perimeter of the second layer as is required in Applicants' claim 1. Further, Zhang, et al. fail to teach or suggest a heat patch including a gas-impermeable cover that is detachably mounted to the outer surface of the gas-permeable first layer, wherein the gas-impermeable cover includes a plurality of portions detachably mounted to the outer surface of the gas-permeable first layer, and wherein at least one of said plurality of portions includes information related to heat generated by the heat patch when one or more of said plurality of portions is removed from said gas-permeable first layer.

Recognizing that Zhang, et al. fail to teach or suggest each and every limitation of Applicants' claim 1, the Office attempts to find each and every element of claim 1 as required by the M.P.E.P. for a determination of *prima facie* obviousness by citing the Usui reference for combination with Zhang, et al.

Specifically, Usui discloses an exothermic device that has an exothermic composition enclosed in a flat pouch formed of a film or sheet. The exothermic composition is formed in two layers including an exothermic reaction layer and a single reaction auxiliary layer. The exothermic reaction layer includes iron powder and the auxiliary layer includes other ingredients. Specifically, a known exothermic composition may be used, which includes, for example, a metal powder, carbon powder, a metallic chloride, water, a water retainer, an inhibitor, a surface active agent, and an anti-foaming agent. The pouch has at least one surface formed of a gas-permeable flat film or sheet in order to allow the exothermic composition enclosed therein to contact oxygen in the atmosphere. Exemplary materials for use as the gas-permeable flat film or sheet include, for example, polymeric materials such as polyethylene, polypropylene, polyamide, polyester, polyvinyl chloride, polyvinylidene chloride, polyurethane, polystyrene, saponified ethylene-vinyle acetate copolymer and ethylene-vinyle acetate copolymer; paper; clothes; and the like. In one particular embodiment, the pouch is formed by placing a gas-tight backing film over the exothermic composition placed on a single gas-permeable film and heat-sealing the peripheries of the gas-permeable film and the backing film.

Significantly, as with the Zhang, et al. reference, the Usui reference fails to teach or suggest a heat patch comprising an enclosure that includes a gas-permeable first layer and a second layer, a heating composition inside the enclosure, and a gas-impermeable cover that is detachably mounted to the outer surface of the gas-permeable first layer, wherein the gas-

impermeable cover includes a plurality of portions detachably mounted to the outer surface of the gas-permeable first layer, and wherein at least one of said plurality of portions includes information related to heat generated by the heat patch when one or more of said plurality of portions is removed from said gas-permeable first layer.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2142 requires a clear articulation of the reasons why the claimed invention would have been obvious. Specifically, the Supreme Court in KSR International Co. v. Teleflex Inc., 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007) noted that the burden lies initially with the Office to provide an explicit analysis supporting a rejection under 35 U.S.C. 103. "[R]ejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."[1] The Court in KSR International further identified a number of rationales to support a conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as laid down in Graham v. John Deere Co. (383 U.S. 1, 148 USPQ 459 (1966). Specifically, as previously required by the TSM (teaching, suggestion, motivation) approach to obviousness, one exemplary rationale indicated requires some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed

[1] In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

invention. Specifically, to reject a claim based on this rationale, the Office must articulate the following: (1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to arrive at each and every limitation of the claimed invention; (2) a finding that there was reasonable expectation of success; and (3) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness. The Office has failed to meet its burden under number (1) above, as the cited references fail to show each and every limitation of Applicants' invention and there is no apparent reason for one skilled in the art to modify and/or combine the references to arrive at each and every limitation. It simply would not have been obvious to one skilled in the art to arrive at Applicants' claimed combinations.

Specifically, as noted above, nowhere do the cited references teach or suggest a heat patch comprising a gas-impermeable cover that is detachably mounted to the outer surface of a gas-permeable first layer, wherein the gas-impermeable cover includes a plurality of portions detachably mounted to the outer surface of the gas-permeable first layer, and wherein at least one of the plurality of portions includes information related to heat generated by the heat patch when one or more of the plurality of portions is removed from the gas-permeable first layer. At best, the Zhang, et al. reference discloses a layer that may be partially covered to reduce air

flow to the heat-generating medium, however, as noted above, Zhang, et al. do not disclose a cover **formed** of a plurality of portions detachably mounted to a gas-permeable layer[2] to accomplish this result as required in Applicants' amended claim 1. Rather, as noted above, Zhang, et al. disclose pieces of tape placed in a convenient place on the device that are removed and **subsequently** placed over portions of the cover to reduce air flow through the cover. Furthermore, although Zhang, et al. describe that the device may employ a removable barrier over the semipermeable membrane(s) or openings to prevent premature activation of the heat-generating medium, Zhang, et al. do not disclose that the pieces of tape used to reduce the air flow are part of the disclosed removable barrier. In contrast to the present invention, where removable portions are included within the cover and are removed to expose a portion of the gas-permeable first layer, the pieces of tape in Zhang, et al. are removed from another portion of the device and placed over the cover such that the exposure of the gas-permeable layer is limited. As such, none of the cited references, alone or in combination, teach or suggest a heat patch comprising a gas-impermeable cover that is detachably mounted to an outer surface of a gas-permeable first layer, wherein the gas-impermeable cover **includes** a plurality of portions detachably mounted to the outer surface of the gas-permeable first layer. Furthermore, no where in either cited reference is it taught or suggested that at least one of said plurality of portions includes information related to heat generated by the heat patch when one or more of said plurality of portions is removed from said gas-permeable

[2] See the instant Specification at page 4, lines 5-6 and lines 21-22.

first layer. More specifically, no where is it even mentioned that it is desirable to include information related to the heat generated by the heat patch.

As there is no teaching or suggestion in the cited references, alone or in combination, to include a gas-impermeable cover in a heat patch wherein the cover is detachably mounted to the outer surface of a gas-permeable first layer, wherein the cover includes a plurality of portions detachably mounted to the outer surface of the gas-permeable first layer, and wherein at least one of said plurality of portions includes information related to heat generated by the heat patch when one or more of said plurality of portions is removed from said gas-permeable first layer, there is no teaching or suggestion to provide the necessary reasoning needed by one of ordinary skill in the art to modify the heat patch cover to arrive at the heat patch as required in claim 1. Accordingly, claim 1 is patentable over the cited references.

Claims 2 and 4-7 are dependent upon claim 1 and are patentable for the same reasons as claim 1 set forth above, as well as for the additional elements they require.

2. Rejection of the Claims 9-12 under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 9-12 under 35 U.S.C. §103(a) as being unpatentable over Zhang, et al. (U.S. Patent No. 5,658,583) and Usui (U.S. Patent No. 5,879,378) in view of Kuratomi, et al. (U.S. Patent No. 4,747,841).

Claim 1, from which claims 9-12 directly or indirectly depend, is discussed above.

The Zhang, et al., and Usui references are discussed above. Significantly, as discussed above, the Zhang, et al. and Usui references fail to teach or suggest a heat patch comprising a gas-impermeable cover that is detachably mounted to the outer surface of a gas-permeable first layer, wherein the gas-impermeable cover includes a plurality of portions detachably mounted to the outer surface of the gas-permeable first layer, and wherein at least one of said plurality of portions includes information related to heat generated by the heat patch when one or more of said plurality of portions is removed from said gas-permeable first layer. Furthermore, the above cited references fail to provide a reasoning for modifying and/or combining the references to arrive at each and every limitation of Applicants' claimed combination. Kuratomi, et al. fail to overcome the above shortcomings.

Kuratomi, et al. disclose a method and apparatus for moxibustion comprising feeding air to a heat generating composition in contact with an herb material comprising moxa. The heat generating composition comprises pyrogen and the herb material is located adjacent to a skin surface. The pyrogen used comprises a heat generating composition consisting of iron powder, carbon, cellulose, chloride, and water. The air causes the pyrogen to generate heat by oxidation, whereby the herb material is heated and vaporized and the generated heat and vapor act on the skin, causing moxibustion effect. An oxygen-impermeable package body is used to pack the pyrogen while not in use, and a gas-permeable internal package is used to house

the pyrogen. The internal package may be formed of woven fabric of synthetic resin, cotton, etc. The exterior of the internal package is covered with the external package formed of a non-permeable material such as a synthetic resin film or thin plate, preventing the pyrogen from contacting the air. The pyrogen can be adjusted for the desired heat generation time and temperature by adjusting the composition of the material or the ventilating structure. Temperatures of 65°C are common at the heat generation source while the temperature at the point of contact with human skin is about 40°C to about 45°C.

Significantly, Kuratomi, et al., as with the Zhang, et al. and Usui references, fail to teach or suggest a heat patch comprising an enclosure that includes a gas-permeable first layer and a second layer, a heating composition inside the enclosure, and a gas-impermeable cover that is detachably mounted to the outer surface of the gas-permeable first layer, wherein the gas-impermeable cover includes a plurality of portions detachably mounted to the outer surface of the gas-permeable first layer, and wherein at least one of said plurality of portions includes information related to heat generated by the heat patch when one or more of said plurality of portions is removed from said gas-permeable first layer.

As the references, alone or in combination, fail to teach or suggest all of the elements of amended claim 1 and, further, there is no motivation or apparent reason to modify and/or combine the cited references to arrive at each and every limitation of Applicants' claim 1, claim 1 is patentable over the cited references.

Claims 9-12 depend directly or indirectly from claim 1 and are thus patentable for the same reasons as set forth above for claim 1 as well as for the additional elements they require.

3. Rejection of the Claim 13 under 35 U.S.C. §103(a)

The limitations of originally filed claim 13 have been included within independent claim 1. Accordingly, reconsideration is requested of the rejection of amended claim 1, including the limitations of originally filed claim 13, under 35 U.S.C. §103(a) as being unpatentable over Zhang, et al. (U.S. Patent No. 5,658,583) and Usui (U.S. Patent No. 5,879,378) further in view of Ingram (U.S. Patent No. 5,366,491).

Claim 1, as amended, is discussed above.

The Zhang, et al., and Usui references are discussed above. Significantly, as discussed above, the Zhang, et al. and Usui references fail to teach or suggest a heat patch comprising a gas-impermeable cover that is detachably mounted to the outer surface of a gas-permeable first layer, wherein the gas-impermeable cover includes a plurality of portions detachably mounted to the outer surface of the gas-permeable first layer. Furthermore, the above cited references fail to provide a reasoning for modifying and/or combining the references to arrive at each and every limitation of Applicants' claimed combination. Ingram fails to overcome the above shortcomings.

Ingram discloses a moist heat pack including a temperature monitoring means attached to the outer surface of the moist heat pack that is specifically calibrated to measure skin surface temperature at the opposite outer skin contacting surface. The

moist heat pack includes an envelope wherein the bottom portion is applied to the subject's skin. A heat source is positioned in the inner body portion of the envelope. The heat source can be selected from any of a number of sources including, but not limited to, microwave stimulation of microwave susceptible material, electric current and heating elements, warm/hot water activation, or an exothermic chemical reaction of components of the heat source. The temperature monitoring means comprises a temperature indicating means calibrated to indicate the actual temperature at the interface of the bottom surface of the envelope and the subject's skin over a predetermined range of temperatures. The temperature monitoring means may be a separate device that may be attached to any therapeutic pack. In a preferred embodiment, the temperature indicating means is a liquid crystal temperature indicating strip. The central zone of the strip denotes skin temperature between 40°C to 45°C. The strip has a subtherapeutic temperature range beginning at temperatures marked below 40°C, which indicates a need to reheat the pack. A third zone indicates temperatures above 45°C to provide a warning to the user to remove the moist heat pack from the skin surface.

Significantly, Ingram, as with the Zhang, et al. and Usui references, fails to teach or suggest a heat patch comprising an enclosure that includes a gas-permeable first layer and a second layer, a heating composition inside the enclosure, and a gas-impermeable cover that is detachably mounted to the outer surface of the gas-permeable first layer, wherein the gas-impermeable cover includes a plurality of portions detachably mounted to the outer surface of the gas-permeable first layer.

Specifically, nowhere do any of the cited references teach or suggest a heat patch comprising a gas-impermeable cover that is detachably mounted to the outer surface of a gas-permeable first layer, wherein the gas-impermeable cover includes a plurality of portions detachably mounted to the outer surface of the gas-permeable first layer, and wherein at least one of the plurality of portions includes information related to heat generated by the heat patch when one or more of the plurality of portions is removed from the gas-permeable first layer. At best, the Ingram reference discloses a liquid crystal temperature-indicating strip that monitors and displays the temperature of the skin. However, as noted above, Ingram does not disclose at least one of a plurality of portions that includes information related to heat generated by the heat patch when one or more of the plurality of portions is removed from the gas-permeable first layer. Applicants initially submit that the strip is not attached to a gas-permeable first layer. In addition, the strip disclosed in Ingram is not detachably connected to the heat patch. Further, the strip in Ingram does not provide information as to what happens when the strip is removed because, in contrast to the present invention, the strip in Ingram is not meant to be removed. If a user were to remove the strip disclosed in Ingram, the strip would not be capable of performing its described and intended function because removal of the strip would prohibit the strip from indicating the actual temperature at the interface of the bottom surface of the envelope and the subject's skin. As such, none of the cited references, alone or in combination, teach or suggest a heat patch comprising a gas-impermeable cover that is detachably

mounted to an outer surface of a gas-permeable first layer, wherein the gas-impermeable cover includes a plurality of portions detachably mounted to the outer surface of the gas-permeable first layer, and wherein at least one of said plurality of portions includes information related to heat generated by the heat patch when one or more of said plurality of portions is removed from said gas-permeable first layer as is recited in Applicants' originally filed claim 13, and as is now recited in Applicants' amended claim 1.

As the references, alone or in combination, fail to teach or suggest all of the elements of amended claim 1 and, further, there is no motivation or apparent reason to modify and/or combine the cited references to arrive at each and every limitation of Applicants' claim 1, claim 1 is patentable over the cited references.

4. Rejection of the Claim 14 under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claim 14 under 35 U.S.C. §103(a) as being unpatentable over Zhang, et al. (U.S. Patent No. 5,658,583) and Usui (U.S. Patent No. 5,879,378) further in view of Lachenbruch (U.S. Patent No. 6,755,852).

Claim 1, from which claim 14 depends, is discussed above.

The Zhang, et al., and Usui references are discussed above. Significantly, as discussed above, the Zhang, et al. and Usui references fail to teach or suggest a heat patch comprising a gas-impermeable cover that is detachably mounted to the outer surface of a gas-permeable first layer, wherein the gas-impermeable cover includes a plurality of portions detachably mounted to the outer surface of the gas-permeable first layer,

and wherein at least one of said plurality of portions includes information related to heat generated by the heat patch when one or more of said plurality of portions is removed from said gas-permeable first layer. Furthermore, the above cited references fail to provide a reasoning for modifying and/or combining the references to arrive at each and every limitation of Applicants' claimed combination. Lachenbruch fails to overcome the above shortcomings.

Lachenbruch discloses a cooling body wrap for inducing hypothermia. The wrap includes a fluid-impermeable, flexible, comfortable envelope, a mixture of from about 20 to about 90 weight percent of alkanes having a carbon chain length of between 10 and 14, and from about 10 to about 80 weight percent of a gel or viscous fluid carrier in which the alkanes are relatively evenly distributed. The mixture is sealed in the envelope. The wrap further includes at least one layer of insulation adjacent to a first side of the envelope and fastening means for fastening the body wrap around a body part. A temperature indicator is preferably included on the wrap so a user knows when to remove it from the freezer. A small thermal window or slit on the outer face of the body wrap or a color-coded window may be used with the wrap to allow the user to view the thermal indicator placed inside the body wrap, which senses the temperature of the envelope. The thermal indicator changes in some visible way, such as a color change, to indicate to the user that the carrier has been cooled to the pre-determined temperature. A color-coded temperature indicator may also be applied directly on the inside or outside faces of the body wrap.

Significantly, Lachenbruch, as with the Zhang, et al. and Usui references, fails to teach or suggest a heat patch comprising an enclosure that includes a gas-permeable first layer and a second layer, a heating composition inside the enclosure, and a gas-impermeable cover that is detachably mounted to the outer surface of the gas-permeable first layer, wherein the gas-impermeable cover includes a plurality of portions detachably mounted to the outer surface of the gas-permeable first layer, and wherein at least one of said plurality of portions includes information related to heat generated by the heat patch when one or more of said plurality of portions is removed from said gas-permeable first layer.

As the references, alone or in combination, fail to teach or suggest all of the elements of amended claim 1 and, further, there is no motivation or apparent reason to modify and/or combine the cited references to arrive at each and every limitation of Applicants' claim 1, claim 1 is patentable over the cited references.

Claim 14 depends from claim 1 and is thus patentable for the same reasons as set forth above for claim 1 as well as for the additional elements it requires.

In addition to the recitations in claim 1, claim 14 further requires that at least some of the plurality of portions are different colors, the colors supplying the information related to heat generated by the heat patch when one or more of the plurality of portions is removed from the gas-permeable first layer. Applicants note, as is addressed above, that the color-coded temperature indicator disclosed in Lachenbruch monitors and displays the temperature of the wrap. Applicants initially

submit that the color-coded temperature indicator is not attached to a gas-permeable first layer as is recited in Applicants' claims. In addition, the disclosed color-coded temperature indicator in Lachenbruch is not meant to be removed from the wrap such that the color-coded temperature indicator is not detachably connected to the wrap. Further, the color-coded indicator would not change colors if it were removed because the color-coded temperature indicator would not function properly if it were removed. Applicants also submit that the color-coded temperature indicator would not provide information as to what happens to the temperature wrap when it is removed from the wrap as is recited in Applicants' claims. Accordingly, Lachenbruch does not describe the limitation "wherein at least one of said plurality of portions includes information related to heat generated by the heat patch when one or more of said plurality of portions is removed from said gas-permeable first layer" as is recited in Applicants' claim 14. As such, claim 14 is patentable over the cited references.

CONCLUSION

In light of the foregoing, Applicants request withdrawal of the rejections of claims 1, 2, and 4-14 and allowance of all pending claims. The Commissioner is hereby authorized to charge any government fees which may be required to Deposit Account No. 01-2384.

Respectfully Submitted,

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